



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 6 1997

Dr. Philip A. Dutermie
Chief Executive Officer
Ayurvedic Concepts Ltd.
6950 Portwest Drive, Suite 170
Houston, Texas 77024

Dear Dr. Dutermie:

This is in response to your letter of December 3, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements for your products:

"GastriCare"

- helps correct minor and common gastro-intestinal imbalances and ensures that the digestive tract works at the optimal level, without the discomfort associated with flatulence, gaseous distension and hyperacidity

"ProstaCare"

- helps manage prostate enlargement, a common condition in men above the age of 50
- helps in relieving urinary discomfort of prostate congestion and normalizes urine flow.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat or mitigate disease, in that "GastriCare" claims to "helps correct minor and common gastro-intestinal imbalances and ensures that the digestive tract works at the optimal level, without the discomfort associated with flatulence, gaseous distension and hyperacidity" and "ProstaCare" claims to help "manage prostate enlargement, a common condition in men above the age of 50" and to help "in relieving urinary discomfort of prostate congestion and normalizes urine flow" (symptoms of Benign Prostatic Hyperplasia). These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that they are subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

**James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition**

Copies:

**FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Dallas District Office, Office of Compliance, HFR-SW100
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200**

Ayurvedic

C O N C E P T S



Health • Science • Tradition

Dec 03, 1996

Dr. Elizabeth A. Yetley
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration - HFS-455
200 C Street SW
Washington, DC 20204

Dear Dr. Yetley,

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement "GastriCare". We estimate that GastriCare will start being sold with these statements of nutritional support on or around December 16, 1996. The statements of nutritional support are as follows :

- Nature's balanced digestion aid formula
- provides an all natural, gentle and safe support of the whole digestive function
- helps correct minor and common gastro-intestinal imbalances and ensures that the digestive tract works at the optimal level, without the discomfort associated with flatulence, gaseous distension and hyperacidity

Very truly yours,

Ayurvedic Concepts Ltd.,
Dr. Philip A. Duterme, Chief Executive Officer